



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-583/S-019

SmithKline Beecham Pharmaceuticals
Attention: Richard Swenson, Ph.D.
Associate Director, U.S. Regulatory Affairs
1250 South Collegeville Road
Mailcode UP 4340
P.O. Box 5089
Collegeville, PA 19426-0989

Dear Dr. Swensen:

Please refer to your supplemental new drug application dated October 27, 2000, received October 30, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Relafen (nabumetone) Tablets.

We acknowledge receipt of your submission dated November 16, 2000.

This supplemental new drug application provides for a revision of the **PRECAUTIONS** and **ADVERSE REACTIONS** sections of the label.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Carmen DeBellas, Chief Project Management Staff, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Jonca C. Bull, M.D.
Deputy Director, and Acting Director,
Office of Drug Evaluation V
Acting Division Director
Division of Anti-Inflammatory, Analgesic, &
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Jonca Bull

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